QUALITY ASSURANCE PLAN

WASHINGTON STATE

DEPARTMENT OF HEALTH

PUBLIC HEALTH LABORATORIES

Revised November, 2000

W.R. Giedt
Public Health Laboraotries

1610 N.E. 150TH STREET

SHORELINE, WASHINGTON 98155-9701

www.doh.wa.gov/phl

206-361-2800

REVIEW SHEET

Date	Section	Change	Initial	Lab Dir. Initial

November 15, 2000

DEPARTMENT OF HEALTH
PUBLIC HEALTH LABORATORIES

PHLabs - QUALITY ASSURANCE PROGRAM

1.0 INTRODUCTION

Quality Assurance is defined as all those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy defined needs.

For the Public Health Laboratories, assurance of quality or management of quality..*is a way of life*. Quality improvement is an ongoing process, achieved by monitoring people, equipment, and materials. It is also achieved through the prevention of problems with careful, detailed planning of all the Laboratories' activities.

A detailed monitoring and evaluation process enables the Laboratories to effectively use their resources to manage the quality of the service they provide. This process involves the ongoing examination of services provided, identification of deficiencies in the services and improvement, as necessary, of the quality of the services. Appropriate monitoring and evaluation activities are ongoing and integrated with other managerial and planning activities throughout the organization.

The monitoring and evaluation process assists in identifying patterns of service that may not be evident when only a case by case review is performed. The process may also identify situations in which a case review is likely to be most useful in identifying correctable deficiencies in service and opportunities to improve service. Although this process will not identify every case of substandard service, monitoring and evaluation helps the organization distinguish situations on which its attention could be most productively focused.

2.0 MISSION OF THE PUBLIC HEALTH LABORATORIES

Provide a wide range of diagnostic and analytical functions for the *assessment* and surveillance of infectious/communicable, heritable/genetic and chronic diseases as well as environmental contamination. Improve the quality *assurance* and analytical performance of clinical and environmental laboratories through training and consultation as well as providing scientific and managerial leadership in developing *public health policy.*

3.0 STATED GOALS/OBJECTIVES OF QUALITY ASSURANCE PROGRAM

Quality Assurance of the Public Health Laboratories is an obligation to the customers the Laboratories serve, the citizens of Washington. Quality Assurance includes all actions planned and implemented to provide confidence that a test result and/or service will satisfy the needs of the customer. This includes control of all processes and procedures which occur within the Laboratories, from the time the sample/specimen is received, through the analytical testing, to the reporting and archiving data. Quality Assurance also extends beyond the physical confines of the Laboratories; from the time a test is requested, through the collection process, to the medical or scientific use and interpretation of the test results.

The Quality Assurance Program was established in order to facilitate achieving the highest standards of quality customer service. The program has been developed to provide:

1) an on-going program to monitor and evaluate the Laboratories' Quality Assurance activities;

2) a working structure for identification and resolution of Quality Assurance problems/concerns;

3) a means for integrating and monitoring information between support and scientific areas;

4) a mechanism for integrating the Quality Assurance within the Laboratories' management and operation;

5) a framework such that the standards established by the laboratories will meet or exceed the standards and requirements for certification of all agencies that certify the Laboratories.

4.0 QUALITY ASSURANCE RESPONSIBILITIES

The Laboratory Director has the overall responsibility for the Public Health Laboratories' Quality Assurance Program. The Quality Assurance Committee is the organizational structure that supports the Lab Director in caring out this responsibility.

4.1 QUALITY ASSURANCE COMMITTEE

Responsibilities include 1) Reviewing laboratory proficiency, 2) Reviews updates of Quality Assurance plans, 3) Maintain Proficiency testing results, 4) In-house inspectors to prepare for inspection, 5) Quality Assurance Issues, 6) Prepare for on-site inspection, and 7) Assist with answers to inspecting officers.

4.2 PUBLIC HEALTH LABORATORIES STAFF

Quality Assurance of the Public Health Laboratories is the responsibility of all staff.

All staff will be responsible for:

1) reporting to their supervisors Quality Assurance problems encountered while performing their duties and responsibilities;

2) assisting in the resolution of problems;

3) providing suggestions for on-going monitoring and developing improvements in service;

4) providing pertinent information to their supervisors as it relates to Quality Assurance.

4.3 SAFETY COMMITTEE

Like Quality Assurance, safety is the responsibility of all Public Health Laboratories' employees. Safety in the laboratory must be routinely practiced and strongly emphasized for a laboratory to function properly. To insure that the Laboratories follows current safety rules and regulations and remains up-to-date on their changes. The Laboratories' safety policies, rules and requirements are documented in the Laboratories' safety manual which is located in the Safety Officer's office and each section.

Safety meetings are held once a month and are attended by a representative from all sections (management and non-management) of the Public Health Laboratories building. Meetings are chaired by an individual elected to that position by the Laboratories' staff. Items discussed include: new safety policies, accident reports and action taken to avoid recurrence, and other safety concerns.

The Safety Committee also has the responsibility for the Laboratories' chemical hygiene program. The Laboratories' chemical hygiene policies, rules and requirements are documented in the chemical hygiene plan manual.

5.0 SCOPE OF SERVICE

The Washington State Public Health Laboratories was established by the legislature in the early 1900's. It was initially located in Seattle in the Alaska Building and moved to the Smith Tower Building. The Laboratories remained there for many years. In 1982, work was started on a 50,000 sq. ft. building located on the Department of Social Health Services Fircrest campus in North Seattle. The new Laboratories was completed and occupied in 1985.

At its inception, the Laboratories was charged with "performing all scientific analysis and tests, chemical, microscopic or other investigations which might be required by the State Board of Health and to make prompt reports of the results thereof." Throughout their long history, the Public Health Laboratories have faithfully and quietly carried out their legislative mandate. To do this, they have undergone dramatic expansion in the programs they offer and the services they provide to the people they serve. These people include Washington health care professionals, environmental and public health policy makers and the citizens of the state.

6.0 QUALITY ASSURANCE PLAN REVIEW

This document will be reviewed annually. The Quality Assurance Committee has responsibility for the manual's review and updating annually. The laboratory director and office directors will review and sign the updated Quality Assurance plans.

Copies of the Quality Assurance plan are maintained in C-1 and also on the LAN.

7.0 DESCRIPTION OF SERVICES

The Public Health Laboratories consists of three offices and Administrative Support:

Office of Public Health Microbiology

Office of Environmental Laboratory Sciences

Office of Newborn Screening

7.1 ADMINISTRATIVE SUPPORT

This unit provides operational and strategic direction and leadership. The office consists of the Laboratory Director, Deputy Director, Training, Buildings and Grounds, and administrative support.

This office offers consultation services in OTS, Quality Assurance, technology transfer, safety and chemical hygiene.

7.2 OFFICE OF PUBLIC HEALTH MICROBIOLOGY

The Office of Public Health Microbiology supports and assists programs of the Department of Health, other state agencies, federal agencies, private and public laboratories, private physicians, family planning agencies, Community Health clinics, and local health departments by providing analytical and diagnostic services.

Mission:
Provide laboratory assessment/surveillance and research activities related to communicable diseases and environmental health problems.

7.3 OFFICE OF ENVIRONMENTAL LABORATORY SCIENCES

The Office of Environmental Laboratory Sciences supports Department of Health Programs, Local Health Jurisdictions and the general public in determining the quality of microbial and chemical conditions within the State. This is accomplished by providing technical consultation, certifying of local governmental and commercial laboratories for Drinking Water testing and providing testing services.

Mission:
Promote and protect the health of the people of the State of Washington by ensuring that quality testing is available to the public for environmental chemical and microbial contaminates.

7.4 OFFICE OF NEWBORN SCREENING

State law and regulation (Chapter 248-103 WAC) require hospitals to submit a blood specimen from every newborn to the Newborn Screening Laboratory (parents may refuse based on religious tenets or practices by signing a refusal form). The Newborn Screening Laboratory is required to perform appropriate screening tests to detect congenital hypothyroidism, phenylketonuria, congenital adrenal hyperplasia, hemoglobinopathies and other heritable disorders as determined by the State Board of Health.

Mission:
To assure that every infant born in Washington who is afflicted with congenital hypothyroidism, phenylketonuria, congenital adrenal hyperplasia, hemoglobinopathies and other heritable disorders as determined by the State Board of Health has access to testing and, if identified, is placed on appropriate treatment as soon as possible after birth.

8.0 IMPORTANT ASPECTS OF SERVICE

The services provided by the Public Health Laboratories support many diverse programs. They can be grouped into the following broad categories:

Ensuring the development of healthy children. Programs, people and facilities in this category include:

1) all infants born in Washington State and their parents;

2) all individuals with or at risk of genetic disease or birth defects;

3) regional genetics clinics;

4) physicians.

Protecting people from environmental hazards and contamination. Programs, people and facilities in this category include:

1) citizens of Washington State;

2) Department of Health environmental programs;

3) local health departments;

4) public water purveyors;

5) other state agencies;

6) federal programs;

7) private laboratories.

Protecting people from disease. Programs, people and facilities in this category include:

1) citizens of Washington State;

2) hospitals and private laboratories;

3) Department of Health programs (HIV/AIDS, STD, family planning clinics, etc.);

4) local health district programs;

5) other state institutions;

6) blood banks;

7) military facilities;

8) Indian health;

9) migrant health;

10) physicians;

11) community health clinics.

9.0 LICENSURE/ACCREDITATION/CERTIFICATION

Accreditation or certification is the recognition for meeting certain predetermined standards conferred upon a facility by a nationally recognized agency. Standards of the accrediting agency assure quality for performance in both administration and analytical testing. The basic principle of accreditation is that the laboratory complies with accrediting agency's standards on a continuous basis.

The Public Health Laboratories are licensed, accredited or certified by the following agencies:

Medicare

Medical Test Site Licensure Program

College of American Pathologists

United States Environmental Protection Agency

United States Food and Drug Administration

Federal Emergency Management Administration

Nuclear Regulatory Commission

These agencies periodically inspect the laboratories they certify. Inspections determine the degree in which a laboratory is following the agency's standards. Copies of the inspection reports are maintained in the units' offices. Corrections will be reviewed by the office director and the Quality Assurance committee.

Any deficiency revealed during an inspection is immediately addressed and corrected by the appropriate laboratory. Reviews and Documentation on action taken to correct the deficiency(s) are sent to the certifying agency with a copy maintained in the OTS office.

Certification/accreditation/licensure by these is also dependent on the Laboratories' performance on proficiency testing. Unsuccessful participation in testing events may result in the loss of certification.

9.1 MEDICARE/MEDICAL TEST SITE LICENSURE PROGRAM

Clinical laboratories in Washington State are required to be certified under the Medical Test Site Licensure Program. Laboratory inspections are performed by inspectors from the Department of Health Office of Laboratory Quality Assurance. For laboratories requiring Medicare certification, Medicare recognizes the Medical Test Site Licensure Program and certifies the laboratory on that basis.

The clinical laboratories of the Public Health Laboratories are certified by Medicare and the Medical Test Site Licensure Program. Inspectors from the Medical Test Site Licensure Program do not inspect the Laboratories due to a conflict of interest, both belong to the same State agency. Hence, inspections are performed by inspectors from Medicare. Inspections are performed at least once every two years. The Medical Test Site Licensure Program recognizes Medicare and certifies the Laboratories on that basis.

The requirements and standards are described in the federal register, dated Friday, February 28,1992, in Part II Department of Health and Human Services, titled Clinical Laboratory Improvements Amendment, 1988 (CLIA88). A copy is maintained in the Quality Assurance Program Manager's office.

9.2 COLLEGE OF AMERICAN PATHOLOGISTS

The College of American Pathologists is a well-recognized clinical laboratory certifying agency. The Public Health Laboratories has maintained accreditation through the College of American Pathologists since the 1970’s. On site inspections by the accrediting agency and self-inspections by the Laboratories alternate year by year.

The College of American Pathologists' requirements and standards are documented in laboratory checklists provided by the agency. Laboratory checklists are composed of relevant questions to each discipline. The questions are of three categories: Phase 0, for informational purposes only; Phase I, considered important and should be corrected if the laboratory is deficient; Phase II, of major importance and, if the laboratory is deficient, must be corrected before laboratory accreditation can be granted.

9.3 ENVIRONMENTAL PROTECTION AGENCY

The State of Washington has primacy for the Federal Drinking Water Program (Safe Drinking Water Act) regulated by the Environmental Protection Agency. Primacy allows states to control their own programs, designates a principal state lab and maintains a certification program using EPA guidelines. All laboratories in the State that analyze public drinking water for chemical, microbiological and radiological contamination must be certified and inspected by the State Certification Program. The PHL is the state principal lab. The PHL's environmental laboratories: Chemistry, Microbiology and Radiation, are inspected and certified by the Environmental Protection Agency, Region 10 Office. All laboratories follow the standards of both the State's Drinking Water Laboratory Certification Program and the Environmental Protection Agency.

The Environmental Protection Agency, Region 10, inspects the PHL every three years. The state labs are inspected every 2-3 years. Inspections follow guidelines described in the "Manual for Certification of Laboratories Analyzing Drinking Water." A copy is maintained in the Certification Program office.

9.4 FOOD AND DRUG ADMINISTRATION

Under provisions of the National Shellfish Sanitation Program, State Laboratory evaluations are a responsibility of the Food and Drug Administration to assure the uniform application of standard procedures and methods in: split samples, the examination of shellfish growing waters, quality control of market shellfish and the monitoring of depuration systems and paralytic seafood poisoning. An additional purpose of laboratory evaluations is to determine the adequacy of facilities, equipment and personnel to perform the level of analytical testing necessary to meet the State's Shellfish Program requirements.

A satisfactory evaluation indicates that the agency recognizes that the laboratory 1) complies with recommended procedures and 2) has the capabilities to produce quality analytical results in support of the State's Shellfish Control Program.

The Food and Drug Administration recommends on-site evaluations at least every 3 years or more frequently if necessary. Inspections follow guidelines set by the agency. The analysts must also demonstrate competence in performing appropriate tests as described in the fourth edition of the Recommended Procedures for the Examination of Sea Water and Shellfish, APHA Official Methods of Analysis of the Association of Official Analytical Chemists, Section 46.117-46.119, Thirteenth Edition, 1980, AOAC, and Interim Guides for the Depuration of the Northern Quahaug, Mercenaria, Marine Health Sciences Laboratory, 1986. The evaluation also includes a review of laboratory apparatus, materials, media preparation, bacteriological procedures, and laboratory techniques.

9.5 NUCLEAR REGULATORY COMMISSION

Nuclear Regulatory Commission is scheduled to evaluate the Laboratory every two years.

9.6 FEDERAL EMERGENCY MANAGEMENT ADMINISTRATION

Federal Emergency Management Administration is scheduled to audit the Laboratory every six years.

10.0 PERSONNEL

10.1 ANALYSTS EDUCATIONAL AND EXPERIENCE REQUIREMENTS

Quality personnel are a major aspect of Quality Assurance. Sufficient education and/or job experience is required for each position of the Public Health Laboratories. The following is a list of educational and experience requirements for all positions involved in testing in the Laboratories. For detailed job requirements see the appropriate Washington State Department of Personnel specifications document.

Laboratory Helper: Graduation from high school, including or supplemented by two semesters of laboratory science courses is desirable.

Laboratory Assistant: Completion of an approved course for laboratory assistants or two years of chemical, or clinical or public health laboratory experience. Training in medical

technology or education in college with courses in laboratory sciences may be substituted, year for year, for expedience.

Laboratory Technician 1: 4 years of experience as a laboratory assistant or higher (college education involving a laboratory science may be substituted, year for year, for the required experience).

Laboratory Technician 2: 5 years of experience as a laboratory assistant or higher (college education may be substituted as stated before) with 1 of the 5 years of experience at a level of a Laboratory Technician 1 or higher.

Laboratory Technician 3: 7 years experience as a laboratory assistant or higher (college education may be substituted as stated before) with 3 of the 7 years of experience at a level of a Laboratory Technician 1 or higher.

Chemist 1: A Bachelor's degree in chemistry or a Bachelor's degree with a minimum of 30 semester or 45 quarter hours of college-level chemistry.

Chemist 2: A Bachelor's degree in chemistry or a Bachelor's degree with a minimum of 30 semester or 45 quarter hours of college-level chemistry and 2 years of laboratory experience as a chemist (or 2 years of experience as a Chemist 1).

Chemist 3: A Bachelor's degree in chemistry or a Bachelor's degree with a minimum of 30 semester or 45 quarter hours of college-level chemistry and 4 years of laboratory experience as a chemist (or 2 years of experience as a Chemist 2).

Chemist 4: A Bachelor's degree in chemistry or a Bachelor's degree with a minimum of 30 semester or 45 quarter hours of college-level chemistry and 6 years of laboratory experience as a chemist (or 1 year of experience as a Chemist 3) with at least 1 year as a chemist lead or supervisor or be recognized and designated, in writing, by the Assistant Secretary as an expert in a chemistry specialty.

Microbiologist 1: A Bachelor's degree in microbiology or a Bachelor' s degree with a minimum of 20 semester or 30 quarter hours of college-level microbiology.

Microbiologist 2: A Bachelor's degree in microbiology or a Bachelor's degree in a major laboratory science with a minimum of 20 semester or 30 quarter hours of college-level microbiology and two years of professional experience in a microbiology laboratory.

Microbiologist 3: A Bachelor's degree in microbiology or a Bachelor's degree in a major laboratory science with a minimum of 20 semester or 30 quarter hours of college-level microbiology and four years of professional experience in a microbiology laboratory.

Microbiologist 4: A Bachelor's degree in microbiology or a Bachelor's degree in a major laboratory science with a minimum of 20 semester or 30 quarter hours of college-level microbiology and six years of professional experience in a microbiology laboratory.

10.2 OFFICE ORGANIZATION

The Public Health Laboratories is a office within EHSPHL of the State of Washington Department of Health. The Laboratories are under the directorship of an Laboratory Director. The Laboratories consist of three offices: Public Health Microbiology, Environmental Laboratory Sciences, and Newborn Screening.

The Office of Public Health Microbiology is divided into eight sections: Reference, Chlamydia, Syphilis Serology, Virology, Human Immunodeficiency Virus (HIV), Mycobacteriology (TB), Enterics, and Sexually Transmitted Diseases and Nose and Throat. A level 3 lead microbiologist has an assigned responsibility for each of the above sections. A lead microbiologist may have the responsibility of more than one section. This person has the signatory authority for test results. The eight sections are condensed into two divisions, each supervised by a level 4 microbiologist. The level 4 microbiologists report directly to the Office Director. Analyte testing is performed by microbiologists and lab technicians.

The Office of Environmental Laboratory Sciences is divided into five sections: Drinking Water Certification, Environmental Chemistry, Parasitology, Environmental Microbiology, and Radiation Chemistry. Environmental and Radiation Chemistry are lead by a Chemist 4/Microbiologist 4, respectively. Drinking Water Certification consists of two Advisory Laboratorians reporting directly to the Office Director of Environmental and Radiation Chemistry.

The Office of Newborn Screening is divided into five sections, of the five analytes tested by the laboratory. Each section is supervised by a level 3 chemist or microbiologist. The coordination and supervision of the laboratory is by a level 4 microbiologist. All supervisors report to the Office Director. Analyte testing is performed by chemists, microbiologists and lab technicians.

The administrative support unit is lead by the Laboratory Director. This unit includes clerical support, Buildings and Grounds, Training, and Safety/QA.

10.3 CONTINUING EDUCATION/TRAINING

In order for the Public Health Laboratories to continue their leadership in providing laboratory consultation as well as reference laboratory services in their function as a state laboratory, the Laboratories' employees must continue to further their knowledge.

The Public Health Laboratories' Training Program addresses the need for effective laboratory bench training as well as updating relevant information and management systems. The Training Program assists state, local and regional health agencies in the development, promotion and delivery of high quality laboratory training resulting in the production of accurate results. This includes training for the staff of the Laboratories.

In cooperation with the Pacific Area Resource Office, a component of the National Laboratory Training Network in Berkeley, California, the Laboratories have developed and implemented several hands-on wet workshops utilizing the existing laboratory training facility. The purpose of the Training Program is to:

1) Plan, develop, organize and implement laboratory bench training and seminars for the Laboratories' staff in addition to technical personnel of other laboratories in Washington State;

2) Design and conduct hands-on laboratory workshops in various laboratory disciplines;

3) Conduct written training needs assessments for staff of the Laboratories as well as for other laboratories of Washington State;

4) Consult with directors from outside laboratories to provide specific training opportunities for their staff;

5) Provide in-service training opportunities for all staff of the Laboratories regardless of position.

10.4 ANALYST COMPETENCY

Insuring that all analysts are competent to perform their analyses is basic Quality Assurance. One means to accomplish this is to have each analyst participate on an appropriate proficiency survey. To insure that all analysts of the Public

Health Laboratories are competent in performing their analyses, the Laboratories have the following policy:

It is the policy of the Washington State Department of Health Public Health Laboratories that analysts who are trained to test a specific analyte and report results on the analyte, will be tested for competency on testing the analyte, annually. The recommended sample/specimen for testing is a current proficiency sample/ specimen. Documentation of the analyst's proficiency testing (results forms) will be maintained by the employee or the office.

10.5 PERFORMANCE EVALUATIONS

The State Department of Personnel requires that all state employees complete a performance evaluation annually. Public Health Laboratories' employees are evaluated by their respective supervisor. Evaluations are maintained by the Department of Personnel in Olympia.

10.6 COLOR BLINDNESS

All microbiology employees are checked for color blindness. Records are maintained in the Office of Clinical Microbiology.

11.0 SAMPLE TEST MANAGEMENT

Sample test management is described in each of the Public Health Laboratories' procedure manuals.

Most samples/specimens are delivered to the Laboratories by the U.S. mail and/or by a courier service.

12.0 ANALYTICAL PROCEDURE MANUALS

Each Office, section or department is required by their certifying agency to have a procedure manual. The contents of the procedure manuals are dependent upon the requirements of each Office or certifying agency. The procedure manuals should include, but not be limited to, requirements for:

- Sample/specimen management
  - Sample/specimen receiving
  - Sample/specimen preparation

- Sample/specimen rejection
- Sample/specimen identification
- Sample/specimen storage

Standard operating procedures

Analytical procedures
- Standards and controls requirements
- Instrumentation
  - Calibration requirements
  - Calibration verification
  - Function checks
- Chemical and reagent requirements

Corrective action for unsatisfactory quality control, standards, etc.

Protocol for comparison of sample results using different methodologies/instrumentation.

Turnaround times

Sample reporting
- Panic values
- Reference ranges
- Cross checking and verifying

Data storage
- Time requirements

The Public Health Laboratories follow National Committee for Clinical Laboratory Standards (NCCLS) document GP-2A3, "Clinical Laboratory Procedure Manuals," procedure manual guidelines.

13.0 QUALITY CONTROL

Control of analytical testing may be broadly divided into internal and external types.

With internal control systems, information from stable control samples, as well as from other samples/specimens, are used to monitor and validate results. Internal quality control procedures are used in real (actual) time to determine if results are valid and can be reported. The main objective of internal quality control is to ensure the day-to-day consistency of measurements.

External quality control refers to a process of retrospectively comparing results from different laboratories through the use of an external source. The major purpose of external quality control is to assess accuracy by comparing results with other laboratories with similar and different methodologies.

13.1 PROFICIENCY TESTING

Proficiency testing is a form of external quality control in which an outside agency submits to the laboratory specially prepared samples/specimens for analysis. The Public Health Laboratories receive proficiency samples from the College of American Pathologists, the NIST approved labs for DW samples, the Centers for Disease Control, the Food and Drug Administration, the Wisconsin State Hygiene Laboratory and Departments of Energy. Appendix B has a listing of proficiency sample analytes from each agency.

The objectives of external quality control are:

1) to provide a measure of the "state of the art" for a test;

2) to provide a measure of the quality of performance of individual laboratories;

3) to supplement internal quality control procedures;

4) to promote improvement of performance;

5) to allow potential customers to evaluate/compare laboratory performance.

Target values are established in a number of ways, some before the samples/specimens are shipped and some after results are reported. Target values are calculated:

1) as a mean of a group of selected "referee" laboratories with known, good performance;

2) by using specimens with values established by measuring in or "spiking" the analyte to be measured;

3) by participant consensus, either as the grand mean of all results or the mean of all results obtained by different laboratories using the same method. For qualitative tests,

the result achieved by the greater than a stated percentage of participants is designated the acceptable result.

Performance standards are chosen by survey personnel based on their professional judgment of the existing state of the art for each test and their usefulness.

When a laboratory receives a shipment of proficiency testing samples/specimens, the laboratory performs the requested tests and returns the results to the agency within a prescribed period of time. As much as possible, survey samples/specimens are treated exactly in the same manner as laboratory samples/specimens. There is no special treatment, such as non-routine replicate analysis, use of a special method, or performing the test with a particular technologist. When special handling is done, a true picture of the laboratory quality is not obtained.

To insure that proficiency samples/specimens are analyzed in the exact same manner as routine samples, the Laboratories have the following policy on proficiency testing.

It is the policy of the Washington State Department of Health Public Health Laboratories that proficiency samples/specimens will be tested in the same manner as routine samples/specimens (unless stated otherwise by their certifying agency). The policy stipulates that:

1) Samples/specimens will be tested using the laboratory's routine methods;

2) Samples/specimens will be tested the same number of times as are routine samples/specimens;

3) Sample/specimens results will not be compared from individuals testing the same sample/specimen simultaneously until after the results have been reported;

4) If possible, samples/specimens will be incorporated into the laboratory's regular workload.

The fundamental purpose of the scoring or valuation of results performed by the proficiency testing agency is to set performance standards for the testing and then decide what levels of performance fall within the range of acceptable results and which are outside and, therefore, unacceptable.

The last step in the external quality control cycle is the review of the laboratory's results and if necessary, the investigation of any unsatisfactory results.

When a single result differs markedly from the target value, clerical or calculation error, analysis of the incorrect sample/specimen or improper sample/specimen preparation may have occurred. The analytical run should be reviewed to verify that analytical and maintenance procedures were followed and internal quality control rules were not violated. If the sample/specimen was saved or additional sample/specimen can be obtained, the test can be repeated or identification of cells and microorganisms can be rechecked.

When results deviate consistently from the target values, significant method problems may exist and a serious evaluation of the reagents, instrument, calibration and procedural steps should be done.

13.1.1 REVIEW OF PROFICIENCY TESTING RESULTS

1) Each analyst reviews and signs the results.

2) Supervisor reviews and signs the results.

3) Office Director reviews and signs the results.

4) Lab Director or designee reviews and signs the results.

13.1.1.1 ENVIRONMENTAL PROTECTION AGENCY

To perform successfully on an Environmental Protection Agency proficiency testing event, the laboratory's results must be within the control limits established by the agency. Control limits for chemistry are usually 2 or 3 standard deviations. For microbiology, it is presence or absence which comply with new presence/absence reporting. All twelve 100% must be correctly identified for each method.

Radiation Laboratories' graded test results are reviewed by their Quality Assurance Coordinator. Results not within specified control limits are investigated. A written response from the analyst who performs the testing, stating reasons for the incorrect result and action taken to avoid recurrence, is filed into the laboratories' proficiency file. Copies of the graded

results, with responses to incorrect results, are sent to the Laboratory Director for review.

Environmental Water Bacteriology's graded result form is forwarded for review and signature to the Office Director, supervisor of the section and analyst. Results that are incorrect require a written response by the testing analyst, stating the reasons for the incorrect result and action taken to avoid recurrence. The graded result form is then forwarded for review and signature to the Laboratory Director.

13.1.1.2 COLLEGE OF AMERICAN PATHOLOGISTS

To perform successfully on a College of American Pathologists' testing survey, the laboratory must achieve at least an 80% success rate. Usually 5 different analyses are required per testing event. Currently, most surveys are distributed 4 times per year.

The graded result form is forwarded for review and signature to the Laboratory Director or designee, Office Director, supervisor of the section, and the analyst that performed the testing. Results that are incorrect require a written response by the analyst, stating the reasons for the incorrect result and action taken to avoid recurrence. The graded result form is forwarded to the Laboratory Director/Deputy Director or designee for review and signature.

13.1.1.3 WISCONSIN STATE LABORATORY OF HYGIENE

To perform successfully on a Wisconsin State Laboratory of Hygiene proficiency survey, the laboratory must achieve at least an 80% success rate. Each event consists of 6 analyses. There are 3 events per year.

The graded result form is forwarded for review and signature from the analyst that performed the testing to the supervisor of the section, then to the Office Director. Results that are incorrect require a written response by the analyst, stating the reasons for the incorrect result and action taken to avoid recurrence. The graded result form is then forwarded to the Laboratory Director for review and signature.

13.1.1.4 DEPARTMENT OF ENERGY

The Public Health Laboratories participates in two of the Department of Energy proficiency programs. They are: 1) The Environmental Measurements (EML) Quality Assessment Program (QAP) and the Radiological and Environmental Measures Laboratory (RESL) Mixed Analyte Proficiency Evaluation Program (MAPEP). For QAP, analytical performance is evaluated on the historical analytical capabilities for individual Analyte/matrix pairs from all participating laboratories. Acceptable is between 15th and 85th percentile of the cumulative normalized distribution. The not acceptable criteria is when the reported values are less than the 5th percentiles or greater than the 95th percentiles.

For MAPEP, the analytical performance is evaluated on the relative bias which the laboratory results and reference value for radiological and inorganic analytes. Acceptable is when the bias is less than 20%. Acceptable with warning is when the bias is greater than 20% but less than 30%. Not acceptable is when the bias is greater than 30%.

13.1.1.5 CENTERS FOR DISEASE CONTROL

The Centers for Disease Control (CDC) distributes samples to be tested on a quarterly basis (monthly for Blood Lead and Fluoride Analyses). The Centers for Disease Control is not a proficiency-testing agency per se. There is no accreditation or certification involved with the testing of analytes from Centers for Disease Control. Summaries of the testing performed is sent to the testing agency for review.

Testing summaries performed by the Newborn Screening Laboratory are reviewed by their Laboratory Coordinator and Office Director. A result summary is sent to the Laboratory Director for review. Results that are incorrect require a written response by the laboratory, stating the reasons for the incorrect result and action taken to avoid recurrence.

Testing summaries from Clinical Microbiology are initially reviewed by the analyst that performed the testing. The graded result form is forwarded for review and signature to the supervisor of the section, then to the Office Director. Results that are incorrect require a written response by the analyst, stating the reasons for the incorrect result and action taken to avoid recurrence. The graded result form is then forwarded to the Laboratory Director for review and signature.

13.2 INTERNAL QUALITY CONTROL

Internal quality control more narrowly describes the techniques and activities by which a department validates and documents proof of the quality of a specific test or service, most notably testing results. This internal quality control system is monitored using both statistical and non-statistical techniques. Internal quality control includes many different procedures, such as checking reagent lot numbers, monitoring temperatures of refrigerators, freezers and heating baths and measuring the concentration of quality control samples.

Internal quality control also refers to a process that involves analyzing specimens with known values and statistically analyzing the resulting data to infer information about patient results and analytical performance.

Laboratory internal quality control systems should also include systems for evaluating performance on a long-term basis. This long-term evaluation of performance is an important part of a general quality assurance program developed to ensure the correct reporting of results.

13.2.1 TEMPERATURE SPECIFIC EQUIPMENT

The monitoring of temperature sensitive equipment is critical in testing for some analytes. This is especially true in microbiology where the identification of organisms is dependent on specific temperature growth characteristics. Temperature monitoring is also important for the proper storage of samples/specimens and reagents.

Not all certifying agencies of the Public Health Laboratories require the monitoring of temperature sensitive equipment. But for the agencies that have requirements, several have guidelines that are common.

Temperature readings will be recorded in appropriate temperature log books daily.

A specific temperature range for operation of the equipment will be established.

Specific instructions for action to be taken for out of range readings will be included on all temperature charts.

All action to correct an out of range reading will be documented on the temperature chart.

Thermometers that are used to monitor temperature dependent equipment should be of good quality that are suitable for reading temperatures within the designated range of the equipment in which it will be used.

All non-certified thermometers used for clinical specimen storage must be checked against a National Institute of Standards and Technology thermometer before it is put in use.

Where applicable all thermometers will be placed in a closed vessel containing a suitable solution for the temperature range of the equipment. For example, freezer thermometers require antifreeze and refrigerator thermometers should be placed in water.

Total immersion thermometers should be encased in a safety container suitable for the water bath.

Thermometers should be used in a manner to prevent temperature shock (rapid and drastic change in temperature).

13.2.2 STERILIZERS

Sterilizers are of major importance to the Laboratories. They are used to sterilize media, glassware and utensils. They are also used to destroy microorganisms on inoculated media prior to the media's disposal.

The steam sterilizers are located in the mycobacteriology and media preparation laboratories, in the glassware washing area, NBS, and building five. For each day in use, the temperature of the sterilizer is documented on a log sheet. Temperatures and time cycles are monitored on charts. All charts are dated and stored within each area. Any deviation of temperature from 121°C ± 2°C requires notification of the supervisor and/or the building maintenance supervisor. (Note: Temperature of 121°C is obtained by using 18-lb. steam pressure.) The sterilizers are on preventative maintenance schedules. All maintenance records are maintained by building maintenance.

The dry oven sterilizer is located in the glassware preparation room. The temperature is monitored by a thermometer placed in a sand container inside the oven. The thermometer is checked semi-

annually for calibration using a certified thermometer. Each run is documented on a log sheet. The temperature should be between 90°C and 93°C. The run is also monitored for sterility by the use of a dated sterility indicator placed on the container to be sterilized.

All sterilizers are checked once a month, with Biological Sterility Indicators, to insure they are functioning properly. The sterilized indicators are submitted to the water bacteriology laboratory for verification of sterility.

Each autoclave should display in clear view the CERTIFICATE OF INSPECTION issued by the Department of Labor and Industries, Division of Building and Construction Safety Inspection Services. This is required by RCW 70.79.320: "The operation of a boiler or unfired pressure vessel without..(an)..inspection certificate... shall constitute a misdemeanor on the part of the owner, user or operator." Required every two years.

13.2.3 WATER QUALITY

Deionized water quality is an important element in laboratory testing. The Public Health Laboratories monitors its deionized water by performing chemistry and microbiology checks. Checks are made monthly for conductivity, silica, free chlorine and pH and Heterotrophic Bacteria Plate Counts. Checks for lead, cadmium, chromium, copper, nickel, zinc, and particulates are performed annually. Conductivity is monitored monthly by an internal probe in the deionized water system and recorded monthly.

Chemistry samples are taken at the pre and post deionized water outlets in the mechanical room and at the hemoglobin laboratory. Microbiology samples are taken at several locations in the building and in building five.

All chemistry, microbiology and conductivity records are reviewed by the Quality Assurance Committee maintained in that office.

The original paperwork for the chemistry test reports/records are maintained by the Environmental Chemistry Laboratory.

Laboratory water, taken from a 3-stage millipore polishing system, exceeds Type I criteria. Type I water is required for standards preparation and for the use of ultra pure water, such as the water used in High Performance Liquid Chromatography and

Inductively Coupled Plasma - Mass Spectometry. Type II water is required for all other usage. The specifications are as follows:

	Type I	Type II	Type III
MAXIMUM BACTERIAL CONTENT (CFU/mL)	10	1000	N/A
MINIMUM RESISTIVITY (MEGOHM-CM) (IN-LINE)	10	1.0	0.1
MAXIMUM SILICATE CONTENT (mg/L Si02)	0.05	0.1	1.0
PARTICULATE MATTER	0.22	N/A	N/A

Readings greater than their limits require the notification of the building maintenance supervisor, the Office Director and/or Quality Assurance Coordinator.

Preventative maintenance is performed by the building maintenance department or by Continental Water Systems. All maintenance records are maintained by building maintenance.

An annual biological suitability test is sent to Central Washington University to test for growth promoting or growth inhibiting substances.

13.2.4 GLASSWARE WASHING

Glassware washing must follow predetermine standards to insure that the glassware is clean and free of contaminants before it can be used. The glassware is washed with a detergent, with the final rinse in deionized water. Organic glassware is also rinsed with solvent (EPA guidelines followed). The glassware is checked for residual using an indicator solution. Records are maintained in the glassware washing room. Sterilization of glassware is performed by the hot oven sterilizer. Inhibitory residue test is performed any time detergent or washing procedure change.

13.2.5 EQUIPMENT PREVENTATIVE MAINTENANCE

Preventative maintenance ensures that equipment continues to function at the level that is required for quality analyses. The Public Health Laboratories has an agreement with the University of Washington Scientific Instruments Department to perform preventative maintenance on many of the Laboratories' equipment. Some instrumentations are on full service contracts with the instrument manufacturers, that includes both the preventative and repair services, on an as needed basis for parts and labor.

The University performs preventative maintenance on all of the Laboratories' microscopes, balances, water baths, incubators and centrifuges. Preventative maintenance is performed at least annually. All other equipment is maintained on as needed basis by in-house parts and labor or by instrument repair personnel by individual offices.

Original records are maintained. The binder also includes all equipment preventative maintenance protocols. Copies of the records are distributed to the appropriate laboratories to file in their records. Biological Safety Cabinets and fume hoods are inspected annually.

Equipment such as water baths, centrifuges, freezers and refrigerators are cleaned at prescribed intervals and documented in preventative maintenance records. This is done by in-house personnel.

13.2.6 MONITORING OF CONTROLS

The EHSPHL does not have definite procedures/ policies on the frequency of controls in a run. Nor do they have procedures/policies for what level of concentration should be used for the controls in an analysis. Each laboratory has in their analytical procedures the frequency and concentration requirements for controls in a run.

The monitoring of control results is an important aspect of the analysis. If any control in a run is out of control, the results of the run cannot be reported with confidence.

In chemistry, for instance, when control limits are set at 2 standard deviations, the samples results are reported at a 95% confidence level. At 3 standard deviations, a 99% confidence level. When controls fall within their statistical limits, results reported are considered valid.

13.2.6.1 ENVIRONMENTAL LABORATORY SCIENCES

The Radiation Laboratories plot all pertinent quality control results on control charts when the analysis is completed. The mean and two and three standard deviations from the mean are calculated by using at least twenty data points. The Laboratories' control limits are set at ± 2 standard deviations (95% confidence level).

For all quality control charts except charts used for alpha spectroscopy, the Laboratories use the following guidelines when a data point or the average of the data points of a run is beyond 2 standard deviations from the mean. The analyst shall follow these steps until the source of the error is found.

A. When the instrument quality control sample results are beyond the 3 sigma control limits:

1) sample counting data is considered not valid;

2) the machine standard is counted at least once more to confirm the instrument is malfunctioning. The analyst shall document in the machine maintenance book, all results beyond 3 standard deviations;

3) if the instrument is determined to be functioning properly, the run of samples is recounted;

4) if the instrument is malfunctioning, the project supervisor shall be notified. Corrective action shall be taken and documented before using the instrument for recounting.

B. When the analysis quality control sample results are beyond the control limits:

1) if the source of the error is not due to instrumentation malfunctioning, the analyst shall recheck the reagents, dilutions, data reduction and other possible sources of errors;

2) the analyst and the project supervisor shall perform an investigation to determine if the analysis needs repeating.

13.2.6.2 MICROBIOLOGY

All media used by the Microbiology laboratories is checked, quality controlled before being used. See section 13.2.7.

The instruments used in the Microbiology laboratories are the Gas Chromatograph, the Enzyme Immunoassay (EIA) and the High Performance Liquid Chromatography (HPLC).

Identification of organisms by HPLC and Gas Chromatography is performed by qualifying the organism's fatty acids and comparing the organism's fatty acids profile to existing libraries.

Gas Chromatography control organisms are analyzed prior to the run. The controls check the calibration. If the controls are not within the specified retention times, the instrument is recalibrated.

The Chlamydia unit uses Ligase Chain Reaction (LCR) to determine the presence or absence of Chlamydia in genital specimens. Other units use EIA for detection of antibody, including HIV and Virus Serology.

Enzyme Immunoassay positive and negative controls are analyzed with each run. If the controls are out, the run is rejected and samples are rerun.

The TB lab uses Gen-Probe DNA probe technology to identify MTB in growing cultures. The TB lab also uses RNA amplification to determine the presence or absence of MTB in sputum specimens.

13.2.6.3 NEWBORN SCREENING

Errors in reporting results are labeled according to protocols outlined in procedure manual in the NBS laboratory. Telephone results are documented.

Analytical performance is monitored on a daily basis by the use of controls and calculated means and coefficient of variation of specific runs. For detailed information consult the Newborn Screening procedure manual.

Controls are used to monitor all runs. Usually high, medium and low controls are included with each run. Results are plotted on control charts. The mean and standard deviations on the charts are calculated using at least 30 observations. The results are acceptable if 1) the control values fall within the ± 2 standard

deviations of the mean and 2) the last five determinations including the current value are not on the same side of the mean, i.e. above or below. The corrective action taken on unsatisfactory results is dependent on the analyte.

The calculated mean of the run is used to monitor the thyroxine results. The result is plotted on a control chart. The mean and the standard deviations are determined from values of specimens tested over a 5-year period. Corrective action is taken when the mean of a run is beyond ± 2 standard deviations.

Coefficient of variation is used to monitor the precision of reagent pipetting for each assay. Following reagent pipetting, radioactive counts per minute of assays from a minimum of ten samples of a batch are used to calculate the coefficient of variation. Runs which have a coefficient of variation greater than 2% require corrective action by counting the whole batch for 0.1 minute. Specimens that have very high and low counts are excluded and reanalyzed the next day.

13.2.6.4 ENVIRONMENTAL LABORATORY SCIENCES

Analytical performance is monitored on a daily basis by the use of blanks, quality control samples, spikes and duplicates.

The laboratory analyzes a known quality control sample with each sample set at a 10%, or greater, frequency. The results obtained are plotted on quality control charts and compared to the true value. Values at greater than 2 standard deviations, but less than 3 standard deviations, will be monitored to observe trends. Values at 3 standard deviations, or greater, indicate the run is out of control. New reagents are made and new calibrations are established. If the analysis of quality control solutions indicates that the method is in control, the samples are reanalyzed. If the method is still not in control, other sources of error such as instrumentation problems are investigated. Samples are not reanalyzed until the method is back in control.

Matrix duplicate spikes are also analyzed with each run at a 10% frequency. These spikes monitor the accuracy of the method and variation in precision due to matrix differences. Accuracy is considered out of limits when the results is not within 80-120% of the expected value. Precision of duplicates is considered out of limits when the relative perceived difference is greater than 20%, in most cases. In each case where the duplicate spikes do not meet accuracy or precision requirements, the sample, and any other samples from the same source, are respiked and reanalyzed.

13.2.6.5 CULTURE MEDIA

Due to the heavy volume of media used by the laboratories, almost all media is prepared in-house.

Media is prepared in batches. A quality control card accompanies each batch. Information on the card includes:

- the media number
- the initials of the preparer
- sterilizer used
- the base lot number
- additives
- date prepared

The media number is a seven digit number. The first five digits is the julian date it was prepared and the last two digits is a number from 00 to 99 depending on when the media was prepared.

All media is checked with the appropriate positive and negative organisms to insure its quality. The results of the checks are written on the quality control card. The card is reviewed and initialed by the analyst using the media.

Media determined unsatisfactory is discarded. The analyst documents on an exception report, the reasons for discarding. The report and the quality control card are forwarded for review and comments, to the level 3 lead microbiologist, level 4 microbiologist supervisor, Office Director supervising the media room and the Quality Assurance Coordinator.

Completed quality control cards are forwarded to the Quality Assurance Coordinator. The cards are reviewed for completeness. Incomplete cards are returned to the responsible area. Finally, the completed cards are then checked against the list prepared by the media room and filed in office R1. All cards must be accounted for.

14.0 TURNAROUND TIMES

Turnaround times are an important aspect of quality assurance. They provide the customer the assurance that results will be reported in a timely manner. Since there is such a diverse amount of testing performed by the Public Health Laboratories, turnaround times are established by each Office. A listing of

turnaround times for several analytes tested by the Laboratories is in Appendix C.

14.1 MONITORING OF TURNAROUND TIMES

14.1.1 ENVIRONMENTAL LABORATORY SCIENCES

Turnaround times are monitored by each project's lead worker. The turnaround times are tracked on the Radiation Database Project Status query revised every two weeks. Turnaround times exceeding their limits are investigated by the project's lead.

Water Bacteriology Laboratory: The monitoring of the turnaround times is performed by all staff in the section.

Parasitology Laboratory: The monitoring of turnaround times is performed by the section's lead. This is performed by reviewing the log book daily for any samples exceeding their turnaround times. In some instances the submitter may be notified.

Food & Shellfish Laboratory: The monitoring of turnaround times is performed by the section's lead. They are monitored by reviewing work cards of samples in process. Due to the nature of the organism it is not uncommon for identifications to exceed their established turnaround times. The turnaround times for shellfish samples is five working days. The submitter may be called on samples that exceed their turnaround times.

14.1.2 MICROBIOLOGY

Enterics Laboratory: The lead of the section monitors the turnaround times. Due to the nature of the organism it is not uncommon for identifications to exceed their established turnaround times. The presumptive results are generally of more importance and the submitter may be called if these turnaround times are exceeded.

Reference Laboratory: The monitoring of turnaround times is performed by the section's lead. Samples exceeding their turnaround times are monitored on a weekly basis by the lead supervisor.

Mycobacteriology Laboratory: The monitoring of turnaround times is performed by the section's lead. This is performed by reviewing the section's read log. The log is generated every Friday and list samples older than eight weeks which have not been reported. The lead investigates all samples in the log. Usually samples that exceed their turnaround time were in need of special handling (e.g. sent to the Centers for Disease Control,

sample needed cleaning up) and the submitter would have been notified before the turnaround time was exceeded.

Sexually Transmitted Disease and Nose and Throat Laboratories: The monitoring of turnaround times is performed by the laboratories' lead. All but the Chlamydia project are monitored by the section's read log. The log is generated every Friday and lists all samples older than five days which have not been reported. The lead investigates all samples on the log.

Chlamydia project's positives and high priority negatives are called to the submitter.

Syphilis Serology Laboratory: The monitoring of turnaround times is performed by the section's lead. VDRLs are monitored by the section's read log. The log is generated every Friday and lists all samples older than five days which have not been reported. The lead investigates all samples on the log. The febrile agglutinations are monitored weekly. Any samples exceeding their turnaround times are investigated.

Virology Laboratory: All specimens received by Virology are entered in an Excel spreadsheet. This is monitored on a weekly basis for overdue specimens, which are then investigated by a lead worker.

Marine Biotoxins: Monitoring of turnaround times are performed by the section's lead or designated assistant at the end of the month.

14.1.3 NEWBORN SCREENING

The Newborn Screening laboratory has developed a report that indicates specimens whose turnaround times have exceeded five days testing for Congenital Hyperplasia, Phenylketonuria and Congenital Adrenal Hyperplasia. This report is included as a part of the office's monthly report. Turnaround times are generated by a computer. Specimens that do not meet the laboratory's target are listed with an explanation of the cause of delay and corrective action is taken.

This report is useful in documenting and trouble shooting the turnaround time for specimens processed by Newborn Screening. Documentation is required on any specimen that does not meet the above criteria. This information is then reviewed by the Office Director.

15.0 INFORMATION SYSTEMS

OVERVIEW

The DOH Public Health Laboratories (PHL) Information Management Systems, which support a wide range of laboratory and administrative functions of the PHL, are run on a Novell LAN/WAN platform with about 110 users locally.

SECURITY

Physical Security:

The LAN/WAN computer equipment is located in an environmentally controlled room (the "computer room") with no exterior walls. The door to this room is secured with a key card lock. Access to the computer room is gained by passing through an outer room, which is occupied by Information Services staff during working hours and is locked during non-working hours.

System Security:

LAN users are assigned a unique login identification and password. Passwords are confidential. Users are required to change their password on a regular basis; standard is every 60 days. Users have two grace logins for changing their password. If a user chooses not to change their password in the grace period, the system automatically denies access. Only authorized Information Services staff can allow access to the users account. If a user tries to login three times unsuccessfully, the system will automatically respond with an Intruder Lockout. The lockout status will last for three weeks, or until manually reset. This lockout status can only be removed by authorized Information Services staff upon the request of the user who has received this status. The File Server records all Intruder Lockout information and Information Services staff regularly monitor this server. Each PHL Office management has established the appropriate level of access for each user when accessing information.

Data Storage and Security:

All lab data is backed up on tape. Backup tapes are kept locally in a secure and environmentally controlled room. Every Wednesday, the main PHL backup tape and the Neometrics backup tape are put into a container and sent to an off-site storage

facility. Backup containers rotate, and are returned two weeks after they are sent out. Once a month a tape is sent to a permanent archive at the off-site facility. Copies of necessary System or Program documentation are also stored off-site. In case of an emergency, any of the off-site information can be retrieved within two hours (by authorized staff only). Backup copies of installed software, master files, etc., are maintained as protection against loss due to operator error or machine malfunction. Hard copy output of confidential data is shredded before recycling.

CURRENT WORKLOAD

The system is in operation 24 hours a day, seven days a week; however, there are scheduled periods of down time for monthly maintenance. These are currently scheduled on Sundays to minimize staff disruption. Unscheduled down time (e.g. crashes, power outages) is less than 1% of the available time.

The majority of users access the computer during the extended work day of 6 AM to 8 PM, Monday through Friday (excluding holidays). Exception users may log in at any time.

The applications utilized by PHL staff have come from a variety of sources. The core application systems are listed below.

Office of Newborn Screening:

State law (RCW 70.83) establishes a requirement of newborn screening for detection of phenylketonuria and other heritable disorders. The goals of the Newborn Screening (NBS) system are to collect and integrate demographic and analytical data for a large number of specimens, provide quality control, including plausibility and validity checks for each specimen, and provide an accurate, legally supportable historical record.

The system assists NBS staff in tracking and analysis of specimens for PKU, CAH, Thyroid, and Hemoglobin tests. This includes database queries, matching birth data with specimen data to monitor hospital compliance for each newborn, billing hospitals, and preparing a variety of reports for lab staff, management, and compliance checking.

Specimen forms are key by BDI, Inc. Data is delivered on diskette on a daily basis. Results are entered by lab staff and collected directly from lab equipment. Birth rosters are

received from hospitals on paper and keyed by BDI and delivered weekly.

Below is a list of some of the reports:

- List of billable specimens & hospital invoices (paper)
- Summary of missing values for each hospital (paper)
- Summary of specimens for each six-month period (microfiche)
- Workload report (paper)
- Turnaround time reports (paper)
- Batch setup reports (paper)
- Analysis reports (paper)
- IEF batch templates (paper)
- Positive results (telephonic)

The system is currently run utilizing Neometrics' Metabolic Screening Database System-III (MSDS-III). This system consists of applications software for processing specimens through the newborn screening array of metabolic tests. The Laboratory portion of MSDS-III includes capabilities for demographic data capture, batch building, results entry, supervisory review, reporting and on-line look-up of all specimens processed through the system. The system is accessed through PC's with LAN access. The entry of the demographic data is done on a data entry system at Brost Data Entry (BDI), transferred by diskette to a PC connected to the NBS Neometric System for core processing. Instrumentation-Merges of Counter Extension Module (CEM) permit the results computed by various instruments to be automatically directed to the appropriate specimen in the MSDS system. This system also incorporates the Case Management System (CMS) of Neometrics'. This allows tracking of all positive results and attaching of follow-up specimens from any PC within the system.

The databases and related files are backed up daily and stored at an offsite location. Other files are backed up daily on PC's within the laboratory.

Office of Public Health Microbiology:

The Microbiology information technology system collects demographics and test results for a large number of specimens in selected clinical areas. These specimen tests are routine, reference, confirmation, and for special studies. The system assists Microbiology staff in tracking and analysis of clinical specimens for chlamydia, syphilis/serology, virology, HIV/AIDS, TB, enteric, and reference.

Demographic information is entered in to the LAN system by lab staff and clerical staff. Test results are entered and verified by lead lab staff. Logbooks, physicians' report, and summary information is generated and printed by lab staff. The entry of data and printing of reports can be done on any PC connected to the PHL LAN. With the exception of TB, the applications were developed in-house. They are PC/LAN based applications that have been converted from applications developed in the PRIME (mini computer) environment.

The TB unit uses an application (LITS) that was developed by the CDC. LITS currently tracks all specimens for TB collecting demographic, test, and test results information. LITS has the ability to identify a previous specimen entered into the LITS system, to enable a patient history to be tracked. Permissions are assigned to each person, who uses LITS defining the options, which may be accessed, by that person. The permissions indicate the level(s) of functions, which may be performed. Each person is identified within LITS by the User Id entered when logging onto the network. A message is displayed indicating that a menu option may not be accessed if an option is selected and the user is not eligible. LITS is in the process of being redeveloped (in SQL) and will be expanded to include the other clinical applications.

E-mail is an integral part of the operation of the Microbiology lab system.

All laboratory data stored on the LAN is backed up daily and stored at an offsite location weekly.

All Microbiology PCs are IBM compatible and connected to the PHL LAN. Print capability within the labs has been standardized with HP compliant printers, with shared access to higher speed/quality printer through the PHL LAN. PCs running the Microbiology database applications are interchangeable.

Office of Environmental Laboratory Sciences:

This office supports the collection and analysis of data for environmental samples. The main areas are radiation, water, shellfish, and lead testing.

Radiation:

Applications are currently run on a variety of hardware, software, and operating systems. The logbook is run on the SQL Server in Olympia. Some counters are connected to the DECnet (Instrumentation network), other counters are connected directly to PCs. All staff is connected to the PHL LAN and has email access.

Applications were developed in MS ACCESS, and PASCAL. Databases are mostly ASCII files. Word processing, spreadsheets, and other PC based applications are used by lab staff.

Environmental Chemistry:

Some PCs are directly connected to lab equipment. Other PCs are stand alone. Staff use word processing, spreadsheets, and other PC based applications. Data is collected on paper.

Environmental testing is done for shellfish biotoxins, food, parasites, drinking and sea water.

Information technology for environmental testing consists of word processing and spreadsheet capability. Environmental lab has limited database capability. Applications developed jointly with Environmental Health Division are being utilized. All information shared with Environmental Health is done via paper reports and e-mail.

Shellfish:

Database information is on a shared Microsoft Access platform maintained by the program in Olympia. Some instrumentation is directly connected to instrumentation but most of the lab activities use paper based.

Administrative Support Unit:

Administrative information technology consists of word processing, spreadsheets, email, project manager and communication applications. All computers are IBM PC compatible and are connected to the PHL LAN. Print capability has been standardized with HP compliant printers with shared access through the PHL LAN.

16.0 EXTERNAL COMMUNICATIONS

16.1 CLIENT COMPLAINTS

Client complaints are usually resolved by the affected office. If the complaint is not resolved by the office, the complaint and its resolution is transferred to the Quality Assurance Coordinator. All actions by the Manager in resolving the complaint are documented. Copies of documentation of the complaint and its resolution are sent to the Laboratory Director. Documentation is filed in the Manager's office.

16.2 COMMUNICATION BREAKDOWNS

Communication breakdowns, like complaints, are resolved by the affected office. If the breakdown is not resolved by the office, the problem and resolution is transferred to the Quality Assurance Coordinator. All actions by the Manager in resolving the breakdown are documented. Copies of documentation of the breakdown and its resolution are sent to the Laboratory Director. Documentation is filed in the Manager's office.

17.0 QUALITY ASSURANCE REVIEW

17.1 ANNUAL REPORT

The Public Health Laboratories' Quality Assurance Program is reviewed annually by the Quality Assurance Committee. An annual report is compiled by the Committee. The report includes results from the past years proficiency testing programs, progress of the Quality Assurance committee during the year, the status of the Quality Assurance Program during the year and future proposed directions.

17.2 QUALITY ASSURANCE COMMITTEE

The Public Health Laboratories' Quality Assurance is also reviewed monthly by a committee composed of representatives from each office. The Quality Assurance committee responsibilities include: examining new Quality Assurance issues, proposing and recommending inter-laboratory Quality Assurance policies and resolving laboratory Quality Assurance problems. The committee is chaired by the Training Coordinator.

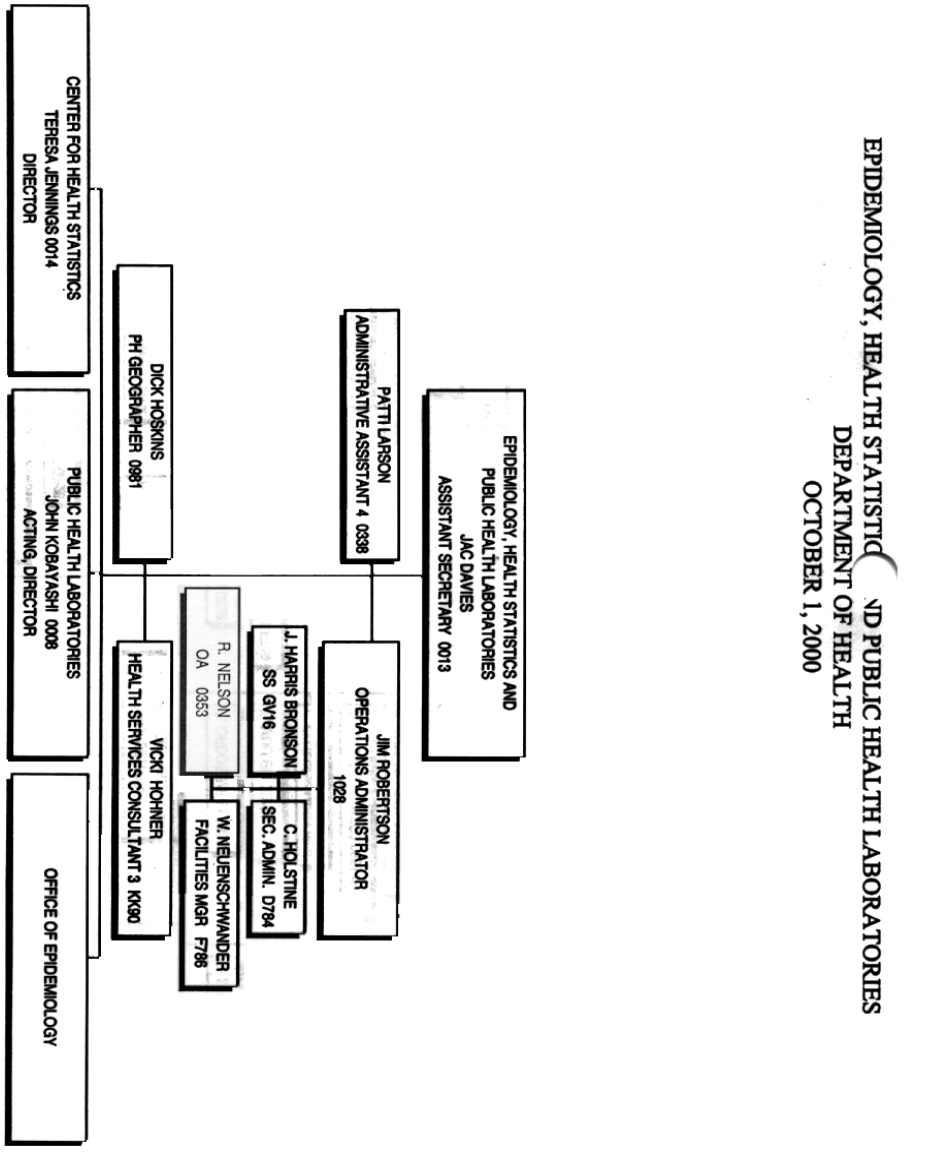
18.0 MEMBERSHIP ORGANIZATIONS

The Public Health Laboratories is an active member with the National Committee for Clinical Laboratory Standards (NCCLS). NCCLS has published some 200 standards, guidelines and committee reports. Documents topics include: safety, chemistry, microbiology and toxicology. The membership includes the receipt of their guidelines and standards.

Many of the guidelines, though directed at clinical laboratories, are appropriate to the Laboratories as a whole. All guidelines, upon receipt, are routed to the laboratories that may have an interest. The guidelines are maintained in office R1.

APPENDIX A - LABORATORY ORGANIZATION

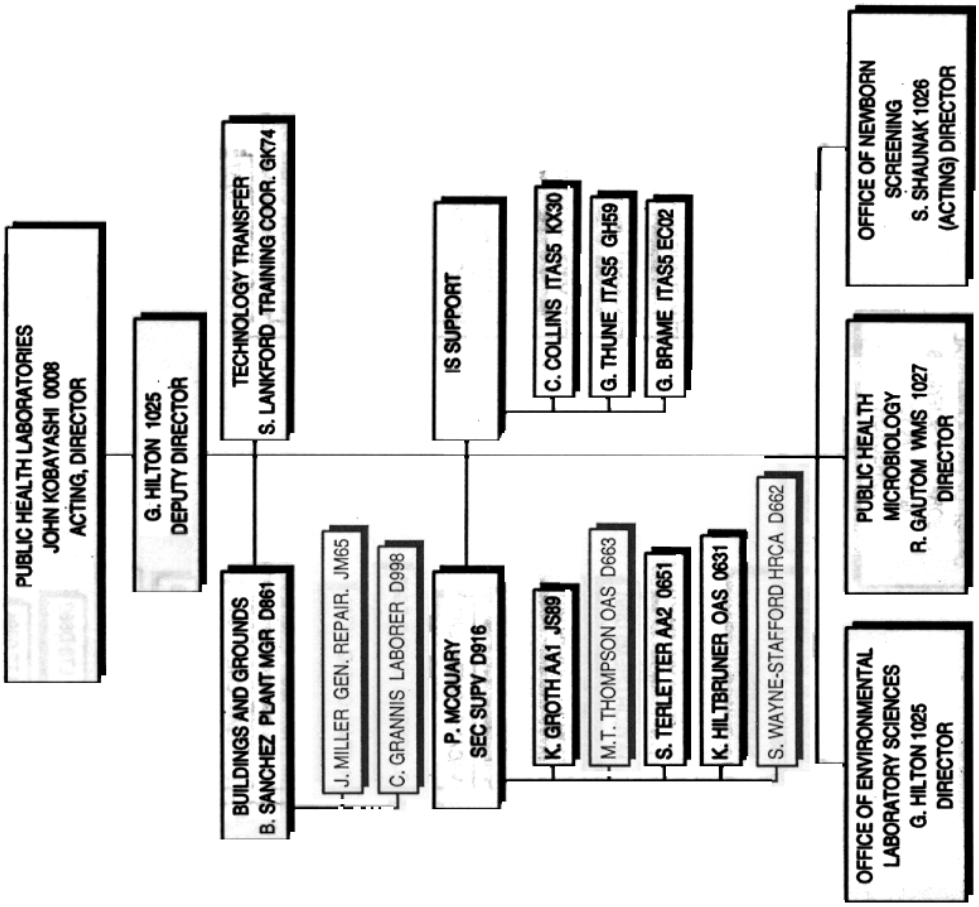
Division Administration



Laboratory Administration

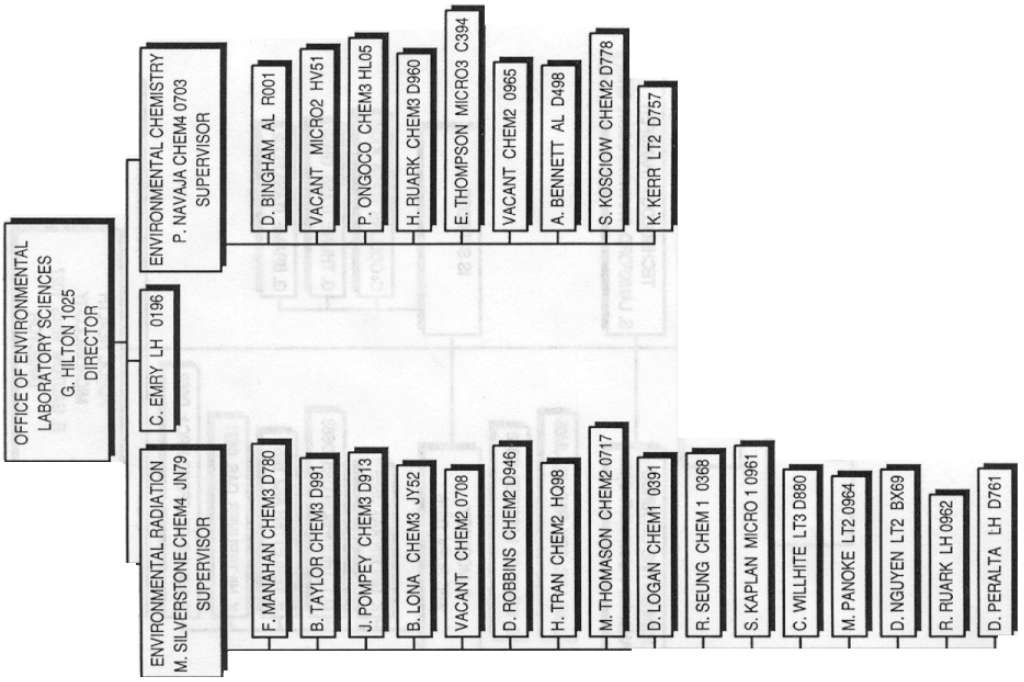
)

EPIDEMIOLOGY, HEALTH STATISTIC ID PUBLIC HEALTH LABORATORIES
DEPARTMENT OF HEALTH
OCTOBER 1, 2000



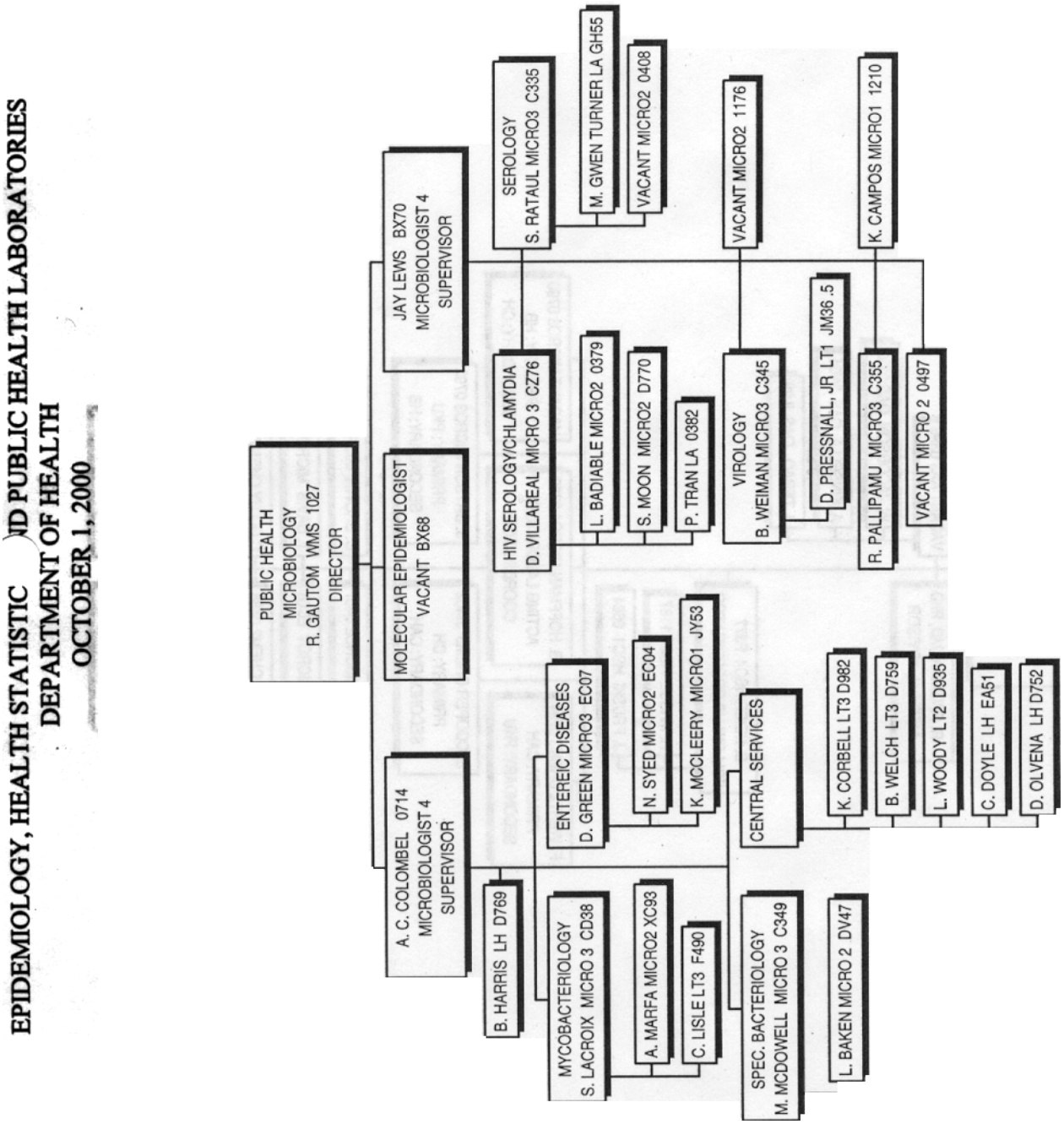
Office of Environmental Sciences

EPIDEMIOLOGY, HEALTH STATISTICS AND PUBLIC HEALTH LABORATORIES
DEPARTMENT OF HEALTH
OCTOBER 1, 2000

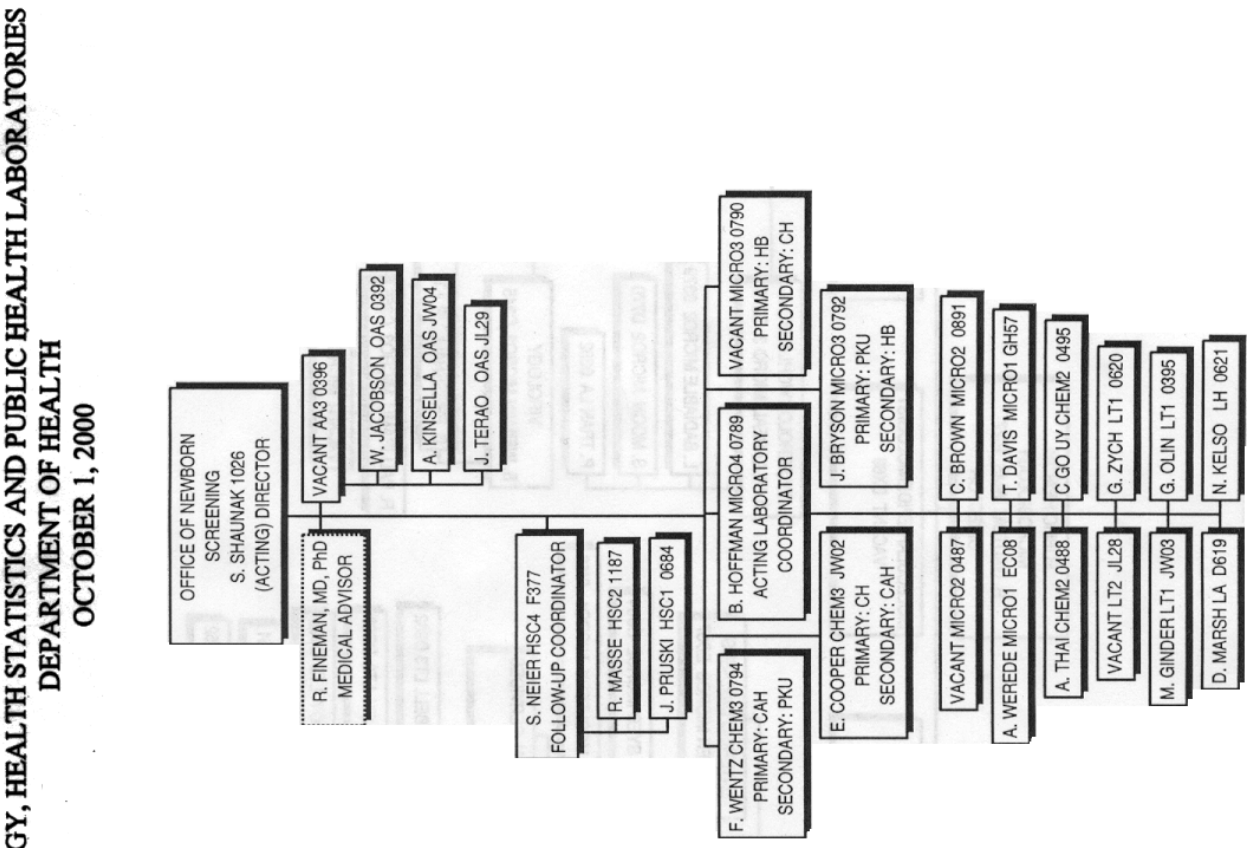


November 15, 2000

Office of Public Health Microbiology



Office of NewBorn Screening



APPENDIX B- PROFICIENCY TESTING ANALYTES

THE COLLEGE OF AMERICAN PATHOLOGISTS

Laboratory	Test	Frequency
Environmental	Blood Lead	4/Yr
Clinical Micro	Bacteriology	4/Yr
Clinical Micro	DFA & EIA/Chlamydia	4/Yr
Clinical Micro	Parasitology	4/Yr
Clinical Micro	Mycobacteriology	2/Yr
Clinical Micro	Mycobacteriology Genetic Testing	2/Yr
Clinical Micro	Virology	3/Yr
Clinical Micro	Herpes/Chlamydia	3/Yr
Clinical Micro	Viral Markers	3/Yr
Clinical Micro	Diagnostic Immunology	3/Yr
Clinical Micro	Syphilis Serology	3/Yr
Newborn Screening	Hemoglobinopathies	3-4/Yr

ENVIRONMENTAL PROTECTION AGENCY

Laboratory	Test	Frequency
Environmental Chemistry	Metals	Annually
Environmental Chemistry	Volatile Organics	Annually
Environmental Chemistry	Residual Free Chlorine	Annually
Environmental Chemistry	Turbidity	Annually
Environmental Chemistry	Total Filterable Residue	Annually
Environmental Chemistry	pH	Annually
Environmental Chemistry	Alkalinity	Annually
Radiation Chemistry	Blind Set for PE Studies (Mixture of Alpha, Beta & Gamma)	1 Set/Yr
Radiation Chemistry	Any Analyte to be Certified (Uranium, Radium, Tritium, Strontium, etc.)	2/Yr for each Analyte
Water Bacteriology	Total Coliform, MF	Annually
Water Bacteriology	Fecal Coli./E. coli, MF	Annually
Water Bacteriology	Total Coliform, MTF	Annually
Water Bacteriology	Fecal Coli./E. coli, MTF	Annually
Water Bacteriology	Total Coliform, P-A	Annually
Water Bacteriology	Fecal Coli./E. coli, P-A	Annually
Water Bacteriology	Total Coliform, Colilert	Annually
Water Bacteriology	E.coli, Colilert	Annually

Water Bacteriology	Total Coliform, Colisure	Annually
Water Bacteriology	E.coli, Colisure	Annually

Department of Energy - EML
Environmental Measurements Laboratory
Quality Assessments Program

Laboratory	Test	Frequency
Radiation Chemistry	Radioisotopes in Water	Semi-Annually
Radiation Chemistry	Radioisotopes in Soil	Semi-Annually
Radiation Chemistry	Radioisotopes in Air Filters	Semi-Annually
Radiation Chemistry	Radioisotopes in Vegetation	Semi-Annually

Department of Energy - MAPEP
Radiological and Environmental Sciences Laboratory
Mixed Analyte Proficiency Evaluation Program

Laboratory	Test	Frequency
Environmental Chemistry	Metals in Water	Annually
Environmental Chemistry	Metals in Soil	Annually
Radiation Chemistry	Radionuclides in Water	Annually
Radiation Chemistry	Radionuclides in Soils	Annually

CENTERS FOR DISEASE CONTROL

Centers for Disease Control provides dried blood proficiency testing material for phenylalanine, thyroid stimulating hormone, thyroxine, 17-hydroxyprogesterone and hemoglobinopathies. Blood samples are also sent to test for blood lead and HIV. Proficiency samples are sent to the Public Health Laboratories quarterly. Water samples are sent to test for fluoride. Fluoride and blood lead samples are sent to the PHL monthly.

APPENDIX C - TURNAROUND TIMES

PUBLIC HEALTH AND ENVIRONMENTAL MICROBIOLOGY

Enterics

Salmonella	Presumptive	48-72 Hours
	Final	7 Days
Shigella	Presumptive	48 Hours
	Final	72 Hours-4 Days
E. coli 0157:H7	Presumptive	72 Hours
	Final	6 Days
C. jejuni	Presumptive	72 Hours
	Final	4-6 Days
Yersinia (Culture)	Presumptive	72 Hours
	Final	5 Days
(Stool)	Presumptive	72 Hours
	Final	3 weeks
Vibrio	Presumptive	48 Hours-4 Days
	Final	72 Hours-4 Days

Water Bacteriology

Drinking Waters	1-7 Working Days
Sea Waters	4 Working Days

Reference

Reference Cultures	7-60 Days
Legionella	
DFA	1-2 Working Days
Cultures	10-14 Working Days
Serology	7-14 Working Days
Environmental	14 Working Days

Cl. botulinum

Presumptive Toxin	24 Hours
Confirmed Toxin	96 Hours
Culture	14-21 Days

F. tularensis

Presumptive	72 Hours
Confirmed	14 Days

Y. pestis

Presumptive	5 Days
Confirmed	14 Days

Brucella spp. 10-31 Days

Parasitology

All Specimens	3 Working Days

Mycobacteriology

Slides	1-2 Working Days
TB (Clinical spec.)	8-10 Weeks
TB Sensitivities	8 Weeks
King Co. Sensitivities	4 Weeks
Reference	4-6 Weeks

STD, Nose and Throat

N. gonorrhoeae

Routine Specimens	3 Working Days
Referred Cultures	4 Working Days
Sensitivities	7 Working Days
Medical Legal	14 Working Days

B. pertussis

DFA	24 Hours
Cultures	10 Working Days

T. pallidum	24 Hours
Group A Strep	48 Hours
Corynebacterium diphtheriae	
Presumptive	24-48 Hours
Confirmed	5 Working Days

Chlamydia Project

Project	3 Working Days
Health Dept. Proj.	3 Working Days

Syphilis Serology

Non-Reactive VDRL	1-2 Days
Positive VDRL	2-5 Working Days
Febrile Agglutinations	5 Working Days

Food

Foodborne Disease Testing	2-7 Days
Shellfish Meat Testing	2-7 Days

Virology

HIV/AIDS	
EIA	2 Days
Western Blot	5 Days

Virus Serology

IgG	
Rubella	10 Days
Rubeola (Measles)	20 Days
IgM Single	
Rubeola (Measles)	10 Days
Rubella	10 Days

Virus Isolation

Respiratory	21 Days Positive
	21 Days Negative
Cutaneous Exception-	
Herpes	21 Days Positive
	21 Days Negative
Other	21 Days Positive
	21 Days Negative

Virus Direct Antigen

Rabies	2 Days
Other	3 Days

Environmental Sciences

Radiation Laboratory

SAMPLE TYPE	STANDARD TURNAROUND TIME	PROJECT
Wipes	Per Customer Request (Can be as quick as 24 hours)	Read Materials (SRI)
Air	2 Weeks	USDOE Air, EFSEC & ATG
Milk	1 Month	EFSEC
DW Program	4 Weeks(if not specified by customer)	State Drinking Water
Soil, Veg. & Water	6 Months	Uranium Mills
Soil & Water	2 Months	Tri-Party

TLDs	2 Weeks	Navy
TLDs	1.5 Months	All other Projects
Ground Water	3 Months	Hanford
Water	1.5 Months	EFSEC
Food	3 Months	USDOE Air, Hanford & EFSEC
Soil	2 Months	USDOE Air, Hanford & EFSEC

The following are factors that effect turnaround time and the prioritizing of samples:

1) Sample preparation time: drying, grinding, sieving, pulverizing, ashing and digestion required for soil, sediment, food and vegetation samples.

2) Rate of radioactive decay of isotopes of interest.

3) Length of time for radioactivity to reach equilibrium.

4) Number and types of samples in the laboratories.

5) Due dates for higher priority samples.

6) Batching of similar test types.

7) Instrumentation malfunction.

8) Additional analysis required after primary analysis performed.

9) The laboratories function in an emergency response mode.

Marine Biotoxins

Paralytic Seafood Poisoning	24-48 Hours
Domoic Acid	4-7 Days

Exceptions may be made for testing samples involving acute intoxication.

Inorganic Chemistry

Complete Inorganic	3 - 4 Weeks
Individual Metals*	1 - 2 Weeks
Group of metals and other non-metal parameters such as conductivity, TDS, alkalinity, etc.*	2 - 3 Weeks
Non-metal parameters (conductivity, alkalinity, TDS, hardness, SO_4, etc.	1 - 2 Weeks
Nitrate	1 Week
Fluoride	1 - 1.5 Weeks
Environmental samples other than water (soil, paint chips, ceramics, etc.)	2 - 3 Weeks

Organic Chemistry

Volatile Organic Compounds	1-2 Weeks 14 days max holding time
Benzene, Toluene and Xylene (BTX)	1-2 Weeks 14 days max holding time
Ethylene dibromide/ Dibromochloropropane	1-2 Weeks 14 days max holding time
Trihalomethanes	1-2 Weeks 14 days max holding time

The above schedule is based on processing an average of 12 to 80 inorganics and 12 to 25 organic analyses monthly. All organics are run on as-received basis, usually same day received.

Turnaround times may increase by up to two weeks if there are analytical or instrumentation problems.

*Dependent on the schedule to run specific metals relative to complete chemistry samples.

NEWBORN SCREENING

SAMPLE TYPE	TURNAROUND TIME
Thyroxin	5 Days
Phenylalanine	5 Days
Congenital Adrenal Hyperplasia	5 Days
Hemoglobinopathies	7 Days
Whole Blood	14 Days

APPENDIX D - QUALITY ASSURANCE POLICIES

The Public Health Laboratories has the following policy on documenting results, entries, etc.:

All entries in logbooks, maintenance logs, work sheets and work cards shall be done in unerasable ink. Entries shall not be erased, removed or obscured in any manner (white-out or white tape). The only acceptable method for change or correction is a double line drawn through the entry with the date and initials of the staff involved. Where applicable chemical logbooks and maintenance logs shall be maintained in bound laboratory style notebooks with all pages left intact. Pages are numbered. Exclusions can be only made by the Office Director.

It is the policy of the Washington State Department of Health Public Health Laboratories that analysts who are trained to test a specific analyte and report results on the analyte will be tested annually for competency on testing the analyte. The recommended sample/specimen for testing is a current proficiency sample/specimen. Documentation of the analyst's proficiency testing (results forms) will be maintained by the employee or the office.

It is the policy of the Washington State Department of Health Public Health Laboratories that proficiency samples/specimens will be tested in the same manner as routine samples/specimens (unless stated otherwise by their certifying agency). The policy stipulates that:

1) Samples/specimens will be tested using the laboratory's routine methods.

2) Proficiency samples/specimens will be tested the same number of times as are routine samples/specimens.

3) Sample/specimens results will not be compared by individuals testing the same sample/specimen simultaneously until after the results have been reported.

4) If possible, proficiency samples/specimens will be incorporated into the laboratory's regular workload.